

Remarks

Based on the above amendments and the following remarks, Applicants respectfully request that the Examiner reconsider and withdraw the outstanding rejections.

Claim Status

Claims 2-3, 5-6, 8-9, 22-23, and 43-45 are currently pending in the application, with claim 45 being the independent claim. Claims 1, 4, 7, and 24-42 were previously cancelled. Claims 10-18 were previously withdrawn from consideration as being drawn to non-elected species. No claims are currently amended.

Examiner Interview

Applicants wish to thank Examiner D. C. Thomas for the telephonic interview held with Applicants agent, Bernadette M. Perfect on March 25, 2010. During the interview the cited reference (Heid *et al.*) and rejections of record were discussed.

At the time of interview, Examiner Thomas agreed with Applicants agent that the Heid reference does not anticipate the currently pending claims. Accordingly, the Examiner indicated that he would discuss with his supervisor as to the proper procedures to withdraw the present rejections under 35 U.S.C. § 102(b).

Claim Rejections Under 35 U.S.C. § 102

I. Claims 45, 2, 5, 6, 8, 9, 43 and 44 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Heid *et al.* (1996, Genome Research vol. 6, pp 986-994) (“Heid”). Applicants respectfully traverse this rejection.

An anticipation rejection under 35 U.S.C. § 102 requires a showing that each limitation of a claim is found in a single reference, practice or device. See *Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983), cert. denied, 465 U.S. 1026 (1984). See also M.P.E.P. 8th ed., § 2131 (rev. 2, May 2004) (“To anticipate a claim, the reference must teach every element of the claim.”).

Applicants respectfully disagree with the present Action’s assertion that Heid teaches a method for analyzing a sample or plurality of samples for the presence of one or more polynucleotide sequences of interest, comprising (i) amplifying at least one of said polynucleotides derived from said sample or said plurality of samples and (ii) amplifying the products of said step (i) by dividing the products of step (i) into a plurality of aliquots and performing real-time PCR of at least one of said aliquots in the presence of (a) at least one of said primer pairs used in step (i); and (b) at least one of said oligonucleotide probes used in step (i).

The Heid reference discloses RT-PCR reactions using total RNA followed by reamplification of target DNA amplicon for use in subsequent cloning. Specifically, Heid states:

“Total RNA was harvested... from cells transfected with a factor VIII expression vector...A factor VIII partial cDNA sequence was generated by RT-PCR... using the PCR primers F8for and F8rev... The amplicon was reamplified using modified F8for and F8rev

primers (appended with BamHI and HindIII restriction site sequences at the 5' end) and cloned into pGEM-3Z... The resulting clone, pF8TM, was used for transient transfection of 293 cells.” See Heid at page 993, first column, first paragraph.

Heid does not anticipate the presently claimed methods for at least the reasons discussed herein. Firstly, Heid does not teach methods involving at least two amplification steps, wherein the first amplification step is performed *in the presence of a plurality of oligonucleotide probes that comprise a label suitable for monitoring amplification as a function of time*. The RT-PCR reactions disclosed by Heid make no mention as to the inclusion of any probes whatsoever. Secondly, Heid does not teach methods involving two amplification steps, wherein the second amplification step comprises *dividing the products of a first step of amplification into a plurality of aliquots*. Again, Heid is completely silent as to any steps taken between the RT-PCR and reamplification steps, much less make mention of any steps for dividing the products of the first RT-PCR reaction into a plurality of aliquots prior to conducting Heid’s reamplification step. Finally, Heid does not teach a second amplification step performed *in the presence of at least one of said primer pairs used in the first amplification step*. Heid, instead, states that the primer pairs used in their reamplification step are “*modified F8for and F8rev primers (appended with BamHI and HindIII restriction sequences at the 5' end)*” (*Id.*, *emphasis added.*) and are therefore not the same as those used in Heid’s RT-PCR reactions.

For at least the reasons discussed above, Heid does not teach each and every element of the claimed invention as is required for a showing of anticipation. Thus, Applicants respectfully

request that the rejection of claims 45, 2, 5, 6, 8, 9, 43 and 44 rejected under 35 U.S.C. § 102(b) be withdrawn accordingly.

II. Claims 3, 22 and 23 are rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Heid in view of Dolganov, et al. (2001, Genome Research 11:1473-1483) (“Dolganov”). Applicants respectfully traverse this rejection for at least the reasons discussed above.

First, Heid does not teach methods involving at least two amplification steps, wherein the first amplification step is performed *in the presence of a plurality of oligonucleotide probes that comprise a label suitable for monitoring amplification as a function of time*. Second, Heid does not teach methods involving two amplification steps, wherein the second amplification step comprises *dividing the products of a first step of amplification into a plurality of aliquots*. Third, Heid does not teach a second amplification step performed *in the presence of at least one of said primer pairs used in the first amplification step*.

Dolganov does not cure the deficiencies of Heid. Thus, Heid in view of Dolganov cannot be used to establish a proper *prima facie* case of obviousness. Thus, Applicants request that the rejection of claims 3, 22 and 23 under 35 U.S.C. § 103(a) be withdrawn accordingly.

Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding rejections. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,
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